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Proposed Maximum Residue Limit PMRL2016-18

Sedaxane

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new use on sugar beet seeds (for import only) to the product label of Vibrance 500FS Seed Treatment, containing technical grade sedaxane, is acceptable. The specific uses approved in Canada are detailed on the label of Vibrance 500FS Seed Treatment, *Pest Control Products Act* Registration Number 30438.

The evaluation of this sedaxane application indicated that the end-use product has value and the human health and environmental risks associated with the new use is acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for sedaxane is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for sedaxane, is as follows.

Table 1 Proposed Maximum Residue Limit for Sedaxane

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Sedaxane	*N*-[2-[1,1′-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide	0.01	Sugar beet roots

[1] ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

The MRL proposed for sedaxane in Canada is the same as corresponding American tolerance as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there is no Codex MRL[1] listed for sedaxane in or on sugar beet commodities on the Codex Alimentarius Pesticide Residues in Food webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL for sedaxane up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limit

Residue data for sedaxane in sugar beets were submitted to support the import of sugar beet seeds treated with Vibrance 500FS Seed Treatment. In addition, a processing study in treated sugar beet roots was reviewed to determine the potential for concentration of residues of sedaxane into processed commodities.

Maximum Residue Limit

The recommendation for the maximum residue limit (MRL) for sedaxane was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for sugar beets.

Table A1 Summary of Field Trial and Processing Data Used to Support MRL

Commodity	Application Method/ Total Application Rate (mg a.i./ 100,000 seeds)[1]	Days After Planting (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Sugar beet roots	Seed treatment/ 7.5	97-155	<0.01	<0.01	No concentration observed in processed commodities

[1] mg a.i./100,000 seeds = milligrams of active ingredient per 100,000 seeds

Based on the dietary burden and residue data, the current MRL of 0.01 ppm established for sedaxane in/on fat, meat and meat byproducts of cattle, goats, hogs, horses, sheep, and milk are adequate.

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of sedaxane. Residues of sedaxane in these crop commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.